



United States
Department of
Agriculture

November 4, 2004

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-19

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Subject: Issuance of a Conditional License for Salmonella Newport
Bacterial Extract

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

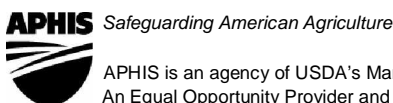
The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to EpiTopix, LLC, Establishment No. 365, Willmar, Minnesota, for the manufacture and distribution of Salmonella Newport Bacterial Extract.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstances. The special circumstance addressed here is the absence of other licensed veterinary biological products for use in control and prevention of disease caused by *Salmonella newport* in cattle.

This conditional license was issued following the acceptance of data supporting product purity, product safety under normal conditions of use (field safety), and demonstration that the product has a reasonable expectation of efficacy. This license will expire in one year. In accordance with 9 CFR Part 102, progress toward regular licensure must be pursued for reissuance of the conditional license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339